REMARKS

Claim Rejections:

Definiteness Rejections

The Examiner rejects claims 124-131, 141, 143 and 145-149 on pages 2-3 of the Office Action on indefiniteness grounds.

For definiteness, a claim need only reasonably apprise those skilled in the art of the utilization and scope of the invention. *Hybritech, Inc. v. Monoclonal Antibodies,* 231 USPQ 81, 94-95 (1986). Words are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. *See* MPEP §§ 707.07(g); 2111.01 (August 2001). Claims are to be given their broadest reasonable interpretation consistent with the specification. *See* MPEP § 2111 (August 2001). In sum, in order to reject the claims on definiteness grounds, it is incumbent on the examiner to show how and why the skilled person having Applicants' specification would not be apprised of the invention by the language-at-issue. The rejections are discussed below.

Claim 124 is rejected by the Examiner for using the term "the body". In response, Applicants amend claim 124.

The Examiner rejected claims 141, 143 and 145-147 for reciting the phrases "the melting point" and "said polymeric chains". In response, Applicants state that the phrase "the melting point" is widely used to indicate 'melting point' of any material in question and a skilled person having Applicants' specification would be apprised of the invention by the language. However, for clarity, Applicants amend claim 147 deleting the words 'the' and 'said' from the phrases. Applicants also amend claim 147 to further clarify the phrase "said polymeric chains".

Anticipation Rejections

On pages 3-4, item 7 of the Office Action, the Examiner rejected the claims 139-141 and 147-149 alleged being anticipated by Hyon *et al.* The Examiner specifically states that "Hyon discloses a method of cross-linking UHMWPE by irradiating, heating and cooling [ ] as claimed in 139-141." Applicants respectfully disagree with the Examiner and note that in order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim term is contained in a single prior art reference. See Scripps Clinic & Research Foundation v. Genentech, Inc., 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81, 90 (Fed. Cir. 1986); see also MPEP § 2131. Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01. Claims are to be given their broadest reasonable interpretation consistent with Applicants' specification. See In re Zletz, 13 USPQ2d 1320, 1322 (Fed Cir. 1989) (holding that claims must be interpreted as broadly as their terms reasonably allow); MPEP § 2111.

Not only must the claim terms, as reasonably interpreted, be present, an allegedly anticipatory reference must enable the person of ordinary skill to practice the invention as claimed. Otherwise, the invention cannot be said to have been already within the public's possession, which is required for anticipation. See Akzo, N.V. v. U.S.I.T.C., 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); In re Brown, 141 USPQ 245, 249 (CCPA 1964).

Applicants provides the following arguments to overcome the 35 USC § 102 rejections:

Hyon does not teach the claimed invention because Hyon does not disclose heating caused by irradiation of PE to cross-link and partially melt, but rather Hyon concerns molding of cross-linked PE after irradiation

The Examiner states that the temperature of polyethylene (PE) before irradiation per Hyon *et al.* is between 90°C and melting point of PE (see col. 4 lines 4-13, 57-60). Yet the temperatures disclosed by Hyon in this passage are to be used in molding of the crosslinked PE after irradiation, and does not concern the temperature of polyethylene during irradiation.

Claim 139-141 clearly recite "[irradiating] to generate sufficient heat to at least partially melt the ultra high molecular weight polyethylene [ ]." This is not what Hyon *et al.* refer to in col. 4, lines 4-16. Hyon *et al.* refer to the heating of the polyethylene after the completion of irradiation by means of a hot press in order to mold. Thus the Examiner has failed to demonstrate that Hyon *et al.* disclose all the limitations recited in the claims 139-141. Therefore, Hyon *et al.* do not anticipate the instant invention. Withdrawal of the rejection is therefore requested.

Hyon does not teach the claimed invention because the Hyon method requires a heating step before irradiation

The Examiner states that "Hyon disclosed a cross-linked polyethylene, which is heated to a temperature below the melting point [ ] as claimed in 147." In response Applicants point out that Hyon *et al.* only refer to (see col 4 lines 5-9) heating of PE before irradiation, when UHMWPE is not crosslinked. In contrast, the instant invention do <u>not</u> require heating of PE <u>before</u> irradiation. Applicants point out that claim 147 recites "[irradiation] generate[s] sufficient heat to at least partially melt the polyethylene", which is not taught in Hyon *et al.* (see col 2 lines 46-55).

Hyon does not teach the claimed invention because UHMWPE does not melt at 80°C

The Examiner states on page 4 lines 5-6 that "Hyon *et al.* discloses an irradiation temperature, which would melt the polyethylene (col.3, lines 39-46)." In response, Applicants respectfully disagree with the Examiner's interpretation of the reference. Applicants point out that the "col. 3, lines 39-46" indicates a temperature of 80°C, which is well below the melting point of UHMWPE. The melting point of UHMWPE is about 137°C. Applicants further point out that claim 148 recites that "the irradiation melts the polyethylene."

Hyon does not instruct the skilled person to heat through irradiation

The Examiner interpreted col. 4, lines 4-16 of Hyon *et al.* as an additional heating step as in claim 149 of the instant application. Applicants respectfully disagree and point out that claim 149 is used when the polyethylene undergoes heating to at least partially melt polyethylene through the energy provided by the irradiation. Claim 149 relates to melting the irradiated (with partial melting during irradiation) polyethylene by an additional heating source. Hyon *et al.* do not disclose an additional heating source. For further clarity, Applicants amend claim 139.

Therefore, the Examiner has failed to demonstrate that each and every claim term is contained in a single prior art reference. Applicants respectfully request the withdrawal of the rejections.

Obviousness Rejections

On pages 4-9, items 8-16 of the Office Action, the Examiner rejected: claims 124, 126-127, 129, 132, and 134-135 as obvious over Hyon *et al.* (US patent No. 6,168,626) in view of Howard, Jr. *et al.* (US patent No. 5,684,124); claim 130 as

obvious over Hyon *et al.* in view of common knowledge; claims 125 and 133 as obvious over Hyon *et al.* in view of Bashir *et al.* (US Patent No. 5,001,206); claim 128 as obvious over Hyon *et al.* in view of Howard and further in view of Dearnaley *et al.* (US Patent No. 5,593,719); 131 and 136 as obvious over Hyon *et al.* in view of Howard and further in view of Parikh *et al.* (US Patent No. 6,005,053); claims 137-138 as obvious over Sun *et al.* (US patent No. 6,174,934) in view of Howard, Jr. *et al.* (US patent No. 5,684,124); claim 142 as obvious over Sun *et al.* in view of Rose *et al.;* claim 143 as obvious over Sun *et al.* in view of Rose *et al.* and further in view of Hyon *et al.;* claim 144 as obvious over Dearnaley *et al.* in view of Howard, Jr. *et al.*; claims 145-146 as obvious over Dearnaley *et al.* in view of Rose *et al.*;

In response Applicants respectfully traverse the rejections and refer the arguments of the above paragraphs made in order to obviate the alleged §102 rejections. As indicated above, Hyon *et al.* do not disclose or suggest each and every claim term of the instant invention, thus, any combination with Hyon *et al.* is improper. In view of the above argument, Applicants further point out that Howard, Jr. *et al.* (US patent No. 5,684,124); the common knowledge as per Examiner; Bashir *et al.* (US Patent No. 5,001,206); Dearnaley *et al.* (US Patent No. 5,593,719); Parikh *et al.* (US Patent No. 6,005,053); Sun *et al.* (US patent No. 6,174,934); and Rose *et al.* do not rectify the deficiencies in Hyon *et al.*

At the outset, applicants note the examiner must show all of the recited claim elements in the combination of references that make up the rejection. When combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by citation to specific evidence in the cited references that (i) there was a suggestion/motivation to make the combination and (ii) there was a reasonable expectation that the combination would succeed. Both the suggestion/motivation and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *W.L Gore v. Garlock, Inc.*, 220

USPQ 303, 312-13 (Fed. Cir. 1983) (holding that is improper in combining references to hold against the inventor what is taught in the inventor's application); *see also* MPEP §§ 2142-43 (August 2001). Thus, the examiner must provide evidentiary support based upon the contents of the prior art to support all facets of the rejection, rather than just setting forth conclusory statements, subjective beliefs or unknown authority. *See In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002).

When an examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) there are elements not contained in the references or within the general skill in the art, (ii) the combination is improper (for example, there is a teaching away or no reasonable expectation of success) and/or (iii) objective indicia of patentability exist (for example, unexpected results). *See U.S. v. Adams*, 383 U.S. 39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986). Applicants submit that the rejections do not meet this test.

Applicants further explain that:

Howard does not teach the claimed invention because the instant invention concerns crosslinked polyethylene

Howard *et al.* do not teach a crosslinked polyethylene. Howard *et al.* describe a polyethylene which is treated with heat and pressure for the generation of the two melting peaks. Aspects of the instant invention, for example, claims 124-138 and 144, on the other hand, teaches a crosslinked polyethylene with multiple melting peaks.

9. Claims 125 and 133 are rejected by the Examiner over Hyon *et al.* in view of Howard Jr. *et al.* and in further view of Bashir *et al.* The Examiner states that "Hyon and Howard disclose a UHMWPE with only one or two (respectively) melting peaks[ ] [and] Bashir teaches in the analogous art of polymers, a polyethylene polymer having 3

melting peaks [ ] as claimed." Applicants respectfully disagree with the Examiner. Applicants point out that claims 125 and 133 describe 3 melting peaks in a UHMWPE radiation and heat treated UHMWPE, which is not what Hyon *et al.*, Howard *et al.* and Bashir *et al.* disclose. Hyon *et al.* only has a single melting peak. Howard *et al.* has only 2 melting peaks in a UHMWPE medical prosthesis that has not been irradiated, and hence are not crosslinked. Therefore, any combination with Howard *et al.* is improper. Finally, Bashir *et al.* describes a (see col 6, lines 24-33) a polyethylene blend showing three melting peaks upon first heating. During the second heat, the polymer shows a single melting peak. Bashir's polyethylene is not crosslinked and has not been irradiated.

Dearnaley does not teach the claimed invention because DECALIN is used in testing crosslink density not in reducing wear

10. Claim 128 is rejected by the Examiner over Hyon *et al.* in view of Howard *et al.* as applied to claims 124 and in further view of Dearnaley *et al.* The Examiner alleges that "Dearnaley teaches [ ] a UHMWPE which is subjected to DECALIN or xylene at temperatures [ ] similar to as claimed [ ], thus reducing wear." Applicants respectfully disagree with the Examiner and indicate that DECALIN is not used in reducing wear in instant invention. Applicants point out that the instant application do not describe the use of DECALIN or xylene extraction to improve the wear resistance of UHMWPE, like Dearnley does (see specification page 27, lines 15-22; page 35, lines 13-29). Claim 128 recites a property of the radiation and heat treated polyethylene in that such polyethylene does not dissolve in DECALIN or xylene under conditions set forth, which is a test evaluating cross-linking.

Parikh does not teach the claimed invention because Parikh's polyethylenes are not crosslinked

11. Claims 131 and 136 stand rejected by the Examiner over Hyon in view of Howard as applied to claims 124 and 132 and in further view of Parikh *et al.* In response, Applicants refer to above arguments and reiterate that any combination of Hyon and Howard is improper. Therefore, further combination with Parikh also is improper. The Examiner states that "Parikh teaches in the analogous field of polymers a polyethylene polymer [ ] which has a crystallinity of less than 50 percent [ ] and a tensile modulus below 940 Mpa [col. 42, line 15] for the purpose of improved mechanical properties." Applicants respectfully disagree with the Examiner's interpretation of Parikh *et al.* disclosure. Applicants point out that Parikh *et al.* describe a blend of polyethylenes, which are not crosslinked. Applicants also indicate that col. 42, line 15 of Parikh *et al.* recites "a 100% modulus of elasticity of at least 140psi" and Parikh *et al.* do not describe "a tensile modulus below 940 Mpa." Besides, Parikh's non-crosslinked blend of polyethylenes, with a modulus less than 940 Mpa, will not result in reduction of wear. According to the instant invention, the polymer has to be crosslinked for improved mechanical properties, for example, improved wear resistance.

Sun does not teach the claimed invention because the heating step is applied at a different stage than the instant method

12. Claims 137 are 138 stand rejected by the Examiner over Sun *et al.* in view of Howard *et al.* The Examiner states that "Sun discloses a method for making a UHMWPE [ ] by irradiating to cross-link [ ], followed by a cooling phase [ ]." Applicants respectfully disagree with the Examiner's interpretation of Sun *et al.* disclosure. Applicants indicate that Sun *et al.* describe a method of heating the irradiated polyethylene to a temperature between 25°C and 140°C. The heating step of Sun *et al.* method is at a different stage than that in the claimed instant method (see for example, page 6 lines 1-4). The Examiner has concluded that Sun *et al.* discloses a method for making a UHMWPE [ ] by irradiating to cross-link (col. 4, lines 39-43) [ ]." Applicants

respectfully disagree with the Examiner's interpretation and indicate that Sun disclosure clearly relates to radiation sterilization of packaged implant (see col. 4, lines 39-43) and is not a method for making a crosslinked UHMWPE. The Examiner also has admitted, however, that "Sun does not disclose [ ] a UHMWPE, which has multiple melting peaks." But the Examiner alleges that "Howard teaches a UHMWPE, which has multiple melting peaks [ ]." Applicants respectfully disagree and refer to above arguments regarding Howard's deficiencies. Therefore the combination of Sun *et al.* and Howard *et al.* will not make the instant invention obvious and there would be no reasonable expectation that the combination would succeed.

13. The Examiner rejects claims 142 as obvious over Sun *et al.* in view of Rose *et al.* The Examiner asserts that "Sun discloses a method of cross-linking UHMWPE to eliminate free radicals [and] Rose teaches irradiation of UHMWPE in doses above 5 Mrads [ ] improves cross-linking without increasing wear." Applicants respectfully disagree with the Examiner's interpretation of Sun *et al.* and Rose *et al.* disclosures. Applicants points out that Sun discloses heating of irradiated polyethylene to a temperature below its melting temperature (see col 5, lines 55-57). Applicants refer to above arguments that Sun's heating step is carried out solely after irradiation, not while the PE is being irradiated. One advantage of the instant invention is that it can provide heating above the melting point to reduce the concentration of free radicals to a level below the detection limit of electron spin resonance. Therefore any combination of Sun *et al.* would be improper and would not yield the claimed invention.

Applicants further point out that Rose describes the use of high radiation dose levels and shows that wear increases with this irradiation, unlike what the Examiner has stated (see page 393, Abstract lines 10-11 of Rose *et al.*). The instant claim also discloses radiation (with more than 5 Mrad) treated UHMWPE with substantially no detectable free radicals, which is the result of the heat generated by irradiation of the

PE, thus improving wear resistance. Applicants amend claim 142 to further clarify of radiation induced heat.

14. The Examiner rejects claims 143 as obvious over Sun *et al.* in view of Rose *et al.* and in further view of Hyon *et al.* In response, Applicants disagree with the Examiner and refer to above arguments regarding Sun *et al*, Rose *et al.* and Hyon *et al.* Applicants reiterate that any combination of Hyon *et al.* is improper based on the arguments presented above. For clarity, Applicants indicate that claims 142 and 143 refer to a dose level above 5Mrad, which are beyond the ranges of Hyon. In fact, Hyon specifically teaches to stay below 5Mrad (see col. 3 lines 62-65 of Hyon *et al.*). Moreover, Sun discloses heat treatment of the irradiated UHMWPE only to a temperature below its melting point (see col. 4, lines 44-46 of Sun *et al.*), unlike the instant invention. Again Rose teaches that wear increases with increasing radiation dose level (see page 393, Abstract lines 10-11 of Rose *et al.*). Therefore the combination of Sun *et al.* and Rose *et al.* will not make the instant invention obvious and there would be no reasonable expectation that the combination would succeed.

15. The Examiner rejects claim 144 over Dearnaley *et al.* in view of Howard Jr. *et al.* The Examiner asserts that "Dearnaley discloses a method to make a medical prosthesis made of UHMWPE [ ] as claimed. Applicants respectfully disagree and refer to above arguments that Howard *et al.* do not rectify the deficiencies in Dearnaley *et al.* Therefore, any combination of Howard *et al.* will not make the instant invention obvious.

16. Claims 145 and 146 stand rejected by the Examiner as being unpatentable over Dearnaley *et al.* in view of Rose *et al.* The Applicants respectfully disagree and point out that Dearnaley *et al.* do not disclose a method of irradiation of polyethylene at a temperature above room temperature (see col. 4, lines 32-39), as the Examiner has stated. Applicants further point out that Dearnaley's immersion of polyethylene in hot

solvent is to extract low molecular weight species (see col. 4, lines 32-39), which is not a method of irradiation of polyethylene at a temperature above room temperature. Thus, this reference has absolutely no pertinence to the claims. Applicants refer to above arguments on the deficiencies of Rose *et al.* Rose *et al.* disclose that higher radiation dose levels increases wear of UHMWPE (see Fig. 3 and the abstract of Rose *et al.*), which indicates increased wear (see line 4 in the abstract of Rose *et al.*: "Wear generally increased with dosage and contact stress."). Thus, Rose *et al.* teach away from the instant invention, at least in regard to the effect of radiation on wear. Therefore any combination of Dearnaley *et al.* and Rose *et al.* is improper and will not make the instant invention obvious.

It is, therefore, clear from the above arguments and the facts that the Examiner has failed to set forth a *prima facie* case of obviousness. Withdrawal thereof is respectfully requested.

Conclusion

In view of this Amendment and Applicant's remarks above, Applicant respectfully submits that the application is in condition for allowance. If any additional fees or additional extensions of time are required with the filing of this Amendment, Applicant respectfully requests such fees and extensions be charged to Deposit Account No. 08-1641.

Respectfully submitted,

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MARKED UP COPY OF AMENDMENTS

In the Specification (Paragraph bridging the pages 27-28):

The UHMWPE of this embodiment has no trapped free radicals, *e.g.*, unsaturated traps-vinylene free radicals. It is preferred that the UHMWPE of this embodiment have a hardness less than about 65 on the Shore D scale, more preferably a hardness less than about 55 on the Shore D scale, most preferably a hardness less than about 50 on the Shore D scale. By hardness is meant the instantaneous indentation hardness measured on the Shore D scale using a durometer described in ASTM D2240. It is preferred that the UHMWPE of this embodiment be substantially not oxidized. The polymeric structure has extensive cross-linking such that a substantial portion of the polymeric structure does not dissolve in **[Decalin]** **DECALIN (decahydronaphthalene)**. By substantial portion is meant at least 50% of the polymer sample's dry weight. By not dissolve in **[Decalin]** **DECALIN (decahydronaphthalene)** is meant does not dissolve in **[Decalin]** **DECALIN (decahydronaphthalene)** at 150°C over a period of 24 hours. Preferably, the UHMWPE of this embodiment has a high density of entanglement so as to cause the formation of imperfect crystals and reduce crystallinity. By the density of entanglement is meant the number of points of entanglement of polymer chains in a unit volume; a higher density of entanglement being indicated by the polymer sample's inability to crystallize to the same extent as conventional UHMWPE, thus leading to a lesser degree of crystallinity.

In the Claims:

124. (once amended) A medical prosthesis for use within **[the]** **a** body, said prosthesis being formed of radiation treated ultra high molecular weight polyethylene having cross-links and multiple melting peaks.

128. (once amended) The medical prosthesis of claim 124, wherein said polymeric structure has extensive crosslinking so that a substantial portion of said polymeric structure does not dissolve in xylene at 130°C or **[decalin]** **DECALIN** at 150°C over a period of 24 hours.

142. (once amended) A method for making a cross-linked ultra high molecular weight polyethylene having substantially no detectable free radicals, comprising the steps of: providing ultra high molecular weight polyethylene having polymeric chains, wherein the ultra high molecular weight polyethylene is at a temperature below its melting point; irradiating said ultra high molecular weight polyethylene with more than 5 Mrads of radiation so as to cross-link said polymeric chains**, wherein the radiation heats the ultra high molecular weight polyethylene**; and cooling said heated ultra high molecular weight polyethylene.

147. (once amended) A method for making a cross-linked polyethylene, comprising the steps of: providing polyethylene at a temperature that is below **[the]** **its** melting point; irradiating the polyethylene so as to (1) cross-link **[said]** polymeric chains **in the polyethylene** and (2) to generate sufficient heat to at least partially melt the polyethylene; and cooling **[said]** **the** heated polyethylene.

149. (once amended) The method according to claim 147, wherein **the partially melted polyethylene is further heated by an additional** **[a]** heating source **[in addition to radiation melts the polyethylene].**